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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT A. VAN TASSEL and MICHAEL KASINKAS

Appeal 2009-012076
Application 10/798,786
Technology Center 3700

Before: JENNIFER D. BAHR, JOHN C. KERINS, and WILLIAM V.
SAINDON, *Administrative Patent Judges*.

SAINDON, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 61-66, 68-71, and 73. The Examiner has indicated claim 67 contains allowable subject matter. Claim 72 has been canceled. We have jurisdiction under 35 U.S.C. § 6(b).

The Invention

The claims are directed to methods for treatment of aneurysms. Claim 61, reproduced below, is illustrative of the claimed subject matter.

61. A method for increasing an adventitial area of tissue comprising:

administering a therapeutically effective amount of a photoactivatable agent to a subject, such that the agent is taken up by the adventitial area of a target tissue;

applying energy to the target tissue to react within^[1] the photoactivatable agent; and

increasing an adventitial area in the area of the target tissue.

References

The Examiner relies upon the following prior art references:

Trauner	US 5,913,884	Jun. 22, 1999
Laufer	US 6,488,673 B1	Dec. 3, 2002

Rejections

- I. Claims 61, 62, 64-66, and 68 are rejected under 35 U.S.C. § 102(e) as anticipated by Laufer. Ans. 3.

¹ “within” appears to be a typographical error. We interpret the claim to mean “with” and suggest, in the event of further prosecution, that this typographical error be addressed appropriately.

- II. Claims 63, 69-71, and 73 are rejected under 35 U.S.C. § 103(a) as unpatentable over Laufer and Trauner. Ans. 4.

SUMMARY OF DECISION

We AFFIRM-IN-PART and enter a NEW GROUND of REJECTION.

OPINION

Anticipation of Claims 61, 62, 64-66, and 68

In relevant part, independent claim 61 requires applying a photoactivatable agent and energy to a target tissue, and increasing an adventitial area² in the area of the target tissue. In general, the photoactivatable agent is activated by the energy to cause fibrosis (scarring), which increases the size of the tissue. Spec. 3:21-26; Laufer, col. 26, ll. 35-37; Trauner, col. 2, ll. 15-28.

The Examiner found that Laufer describes applying light energy to the inner wall of a vessel (lung airway) after applying a photoactivatable agent that is “necessarily taken up by the wall and the adventitial area of the vessel.” Ans. 3. Appellants argue that the Examiner does not provide a basis in fact or technical reasoning that the heating of the inner wall of the vessel, as taught in Laufer, will inherently heat the adventitial area of the tissue. Appeal Br. 9-10. Claim 61, however, does not require applying heat (or any other particular energy form) to the adventitial area of the target

² A dictionary definition of “adventitia” is “[t]he outermost membranous covering of an organ or structure, especially the outer coat of an artery.” *The American Heritage Medical Dictionary* (2007) (retrieved from <http://www.credoreference.com/entry/hmmedicaldict/adventitia>) (last visited May 11, 2011).

tissue but rather to the target tissue. Accordingly, Appellants' argument is not commensurate with a limitation found in claim 61. *See In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) (limitations not appearing in the claims cannot be relied upon for patentability).

Appellants next argue that Laufer does not teach or suggest increasing an adventitial area in the area of the target tissue. Appeal Br. 11. The Examiner does not identify any particular passage in Laufer regarding an adventitial area of a lung airway. The Examiner instead finds that the photoactivatable agent necessarily reaches the adventitial area and the energy inherently reaches the photoactivatable agent (thus, presumably, increasing the adventitial area via fibrosis). Ans. 5. The Examiner adds, "since the method steps [in] Laufer ... are the same as those claimed, then one can logically conclude that the human body would react the same with the same result." *Id.* Therefore, the first issue is whether the Examiner has shown, under the principles of inherency, that Laufer describes increasing an adventitial area in the area of the target tissue in the manner required by claim 61.

"Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (quoting *Hansgird v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939)) (emphasis added). Thus, to permit us to sustain the Examiner's finding that Laufer inherently describes increasing an adventitial area, the record "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). Laufer uses a light delivery device to irradiate

the smooth muscle (inner wall) of the airways in a lung to induce fibrosis. Col. 26, ll. 35-37. The device irradiates the airway walls from inside, adjacent to the airway. Col. 27, ll. 4-6, fig. 37 (depicting the device in the airway). Laufer does not describe the location of the adventitial layer corresponding to the airway, any reactions occurring in an adventitial layer, or how far into the tissue the radiation penetrates. The Examiner does not make any finding as to how deeply the radiation penetrates or if this amount would be sufficient to induce fibrosis in an adventitial area. Thus, even if the adventitial area were only “microns away,” as suggested by the Examiner (Ans. 5), the record does not set forth a sufficient factual basis to support the Examiner’s finding that enough energy *necessarily* reaches the adventitial area to increase its area. *See Continental Can*, 948 F.2d at 1268. Consequently, we find that the Examiner has not established that Laufer anticipates the subject matter of claim 61. The Examiner’s rejection of dependent claims 62, 64-66, and 68 is likewise in error.

Obviousness of Claims 63, 69-71 and 73

Claim 63 depends from claim 61 and further requires local administration of the photoactivatable agent. The Examiner found that Trauner teaches the option of local or systemic administration of a photoactivatable agent. Ans. 4; *see also* Trauner, col. 7, ll. 13-31 (choice generally depends on “size, nature, and location” of treatment area). Appellants argue that Trauner does not teach a photosensitizer agent delivered to an adventitial area of the target tissue. Appeal Br. 12. Appellants add that the photosensitizer in Trauner is only targeted to macrophages and myofibroblasts. *Id.* Claim 63 does not require targeted delivery of an agent to the adventitial area but rather local administration of

the agent to a subject, and that the agent is taken up by the adventitial area of a target tissue. Thus, the delivery could be elsewhere locally, so long as the agent is taken up by the adventitial area. *See, e.g.*, Trauner, col. 7, ll. 21-31 (suggesting to wait for the agent to move to target site and reach optimal concentration). The adventitial area need not be the target or site of injection. Appellants additionally state that the cited references “fail to teach or suggest each limitation of the claimed invention.” Appeal Br. 13. However, Appellants have not identified a claim limitation that is not taught or suggested by the references, nor have Appellants set forth any persuasive arguments as to why the Examiner’s rejection is in error. *See Ex parte Belinne*, 2009-004693, slip op. at 7, 8 (BPAI Aug. 10, 2009) (designated as an “Informative Opinion”) (available at <http://www.uspto.gov/web/offices/dcom/bpai/its/fd09004693.pdf>) (last visited May 2, 2011) (*citing* 37 C.F.R. § 41.37 (c)(I)(vii)); *see also Belinne* at n.2 (“A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim”). In light of Appellants’ arguments, we are not persuaded that the Examiner erred in rejecting claim 63.

Independent claim 69 requires external irradiation of the target region. In relevant part, the Examiner found that Trauner teaches both internal and external irradiation. Ans. 4; *see also* Laufer, col. 11, ll. 10-25 (internal), Trauner, col. 7, ll. 44-60 (internal or external). Appellants argue that neither Laufer nor Trauner “teach application of the agent to the adventitial layer.” Appeal Br. 13. However, claim 69 does not require application of the agent to the adventitial layer. Appellants additionally state that the cited references “fail to teach or suggest each limitation of the claimed invention.” Appeal Br. 13. However, Appellants have not identified a claim limitation that is not taught or suggested by the references, nor have Appellants set

forth any persuasive arguments as to why the Examiner's rejection is in error. *See Belinne*, slip op. at 7, 8, n.2. Appellants add that the cited references teach away from the claimed invention, but fail to point to any passage that disparages, discredits, or otherwise discourages external light delivery. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (prior art does not teach away from claimed subject matter merely by disclosing a different solution to a similar problem unless the prior art also criticizes, discredits, or otherwise discourages the solution claimed). Quite to the contrary, Trauner explicitly teaches external light delivery. Col. 2, ll. 52-54. In light of Appellants' arguments, we are not persuaded that the Examiner erred in rejecting claim 69. Appellants do not raise any separate arguments for dependent claim 73, which falls with claim 69. 37 C.F.R. § 41.37(c)(1)(viii).

Independent claim 70 requires internal irradiation of the target region. The Examiner found that Trauner teaches both internal and external irradiation. Ans. 4. Appellants set forth unpersuasive arguments regarding "application of the agent to the adventitial layer" and failing to "teach or suggest each limitation," similar to those we found unpersuasive with respect to claim 69. Appeal Br. 14. Appellants also argue that Trauner teaches that high doses of therapy inhibit fibrosis, and that the necessary heat to reach the outer surface (adventitial area) would therefore inhibit fibrosis (presumably in the adventitial area). *Id.* However, Appellants' arguments regarding the quantity of heat required to reach the adventitial area are unpersuasive because they are speculative and not based on facts or technical reasoning. Appellants have not established the location of the adventitial area corresponding to the target tissue or the quantity of heat required to cause fibrosis in that area. Further, neither Laufer nor Trauner

are limited to heat energy. Trauner, col. 7, ll. 32-35 (light wavelength and intensity vary depending on photosensitizer used); Laufer, col. 11, ll. 16-20 (using radiant, laser, radio frequency, microwave, heat energy, or mechanical energy). The absorption in the body of these other forms of energy varies; their use may not necessitate high energy doses to reach the adventitial area, especially given internal irradiation options. *See, e.g.,* Trauner, col. 7, ll. 47-51 (near infrared allows deeper tissue penetration). Even assuming Appellants' proffered scenario, *arguendo*, the record before us seems to suggest that it would likely result in no fibrosis to the inner layer but some fibrosis to the outer layer because the outer layer would receive less heat (assuming some heat is absorbed by the inner and intermediate layers as it travels to the adventitial area). *See* Trauner, col. 2, ll. 24-28 (low doses hasten fibrosis, high doses inhibit fibrosis). This would be a favorable result because the inner layer would not swell to the point of closing the vessel and the outer layer would absorb a fibrosis-inducing low dose. *See, e.g.,* Laufer, col. 9, ll. 10-12 ("it is preferable not to create so much fibrotic tissue that the airway closes"). Accordingly, we do not find Appellants' arguments regarding claim 70 persuasive. Appellants do not raise any separate arguments for dependent claim 71, which falls with claim 70. 37 C.F.R. § 41.37(c)(1)(viii).

NEW GROUND OF REJECTION

Pursuant to our authority under 37 C.F.R. § 41.50(b), we reject independent claim 61 under 35 U.S.C. § 103(a) as unpatentable over Laufer and Trauner.

We are persuaded the Examiner erred in finding claim 61 anticipated by Laufer but not in concluding that claim 63 is unpatentable over Laufer

and Trauner. Claim 63 depends from claim 61 and thus contains each limitation of claim 61. 35 U.S.C. § 112, fourth paragraph. The conclusion that the subject matter of claim 63 is unpatentable over Laufer and Trauner implies that the subject matter of claim 61 is likewise unpatentable over Laufer and Trauner. *See Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007) (when a dependent claim is “found to have been obvious, the broader claims . . . must also have been obvious”). In an abundance of caution, we denote the Examiner’s implied obviousness rejection of claim 61 (i.e., the obviousness rejection of claim 63) as a new ground of rejection.

DECISION

For the above reasons, we reverse the Examiner’s decision regarding claims 61, 62, 64-66, and 68. We affirm the Examiner’s decision regarding claims 63, 69-71, and 73. We enter a new ground of rejection for claim 61 as unpatentable over Laufer and Trauner.

FINALITY OF DECISION

Regarding the affirmed rejection, 37 C.F.R. § 41.52(a)(1) provides “Appellant[s] may file a single request for rehearing within two months of the date of the original decision of the Board.” In addition to affirming the Examiner’s rejection of one or more claims, this decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.” 37 C.F.R. § 41.50(b) also provides that Appellants, **WITHIN TWO MONTHS FROM THE DATE OF THE DECISION**, must exercise one of the following two options with respect to

the new ground of rejection to avoid termination of the appeal as to the rejected claims:

- (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner....
- (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record....

Should Appellants elect to prosecute further before the Examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome. If Appellants elect prosecution before the Examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv) .

AFFIRMED-IN-PART; 37 C.F.R. § 41.50(b)

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